

LIST OF CLAIMS

1. (Currently Amended) A formed product composition for releasing an active ingredient disintegration in a large intestine part of a lower gastrointestinal tract, comprising:

(1) an inner core comprising an active ingredient <c> to be delivered to the large intestine;

(2) a disintegration layer surrounding said inner core comprising particles comprising a compound <A> having a molecular weight of 1,000 or less and having a disulfide bond and a polymer <B> having a molecular weight of above 1,000 which forms a matrix in which said particles are dispersed and having a property of being decomposed by enterobacteria, and/or a property of being softened, swelled or dissolved due to a decrease in pH in the range of from about 6.8 to about to a lower pH present in the large intestine, wherein the disintegration layer is stable in a small intestine at a pH of about 6.8, but when in the large intestine, the particles of compound <A> are dissolved forming microfine holes in the matrix of polymer <B> for liquid of the large intestine contents to enter the matrix; and

(3) optionally an enteric coating surrounding said disintegration layer.

2. Canceled

3. (Currently Amended) The formed product A ~~composition~~  
~~for disintegration in lower gastrointestinal tract~~ according to  
claim 1 ~~or 2, characterized in that~~ wherein the matrix further  
contains a substance that controls disintegration rate in the  
large intestine of the lower gastrointestinal tract.

4. (Currently Amended) The formed product A ~~composition~~ ~~for~~  
~~disintegration in lower gastrointestinal tract~~ according to claim  
1, wherein ~~characterized in that the~~ compound <A> is ~~any compound~~  
~~optionally at least one compound~~ selected from the group consisting  
of L-cystine, D-cystine, DL-cystine, diglycyl cystine, cystamine,  
L-cystinyldiglycine, glutathione disulfide, and thioglycolic acid  
disulfide or  $\text{HOOC-R-S-S-R-COOH}$  + wherein R represents a lower  
alkylene group).

5. (Currently Amended) The formed product A ~~composition~~ ~~for~~  
~~disintegration in lower gastrointestinal tract~~ according to claim  
1, ~~characterized in that the~~ wherein polymer <B> is at least one  
polymer ~~any polymer optionally~~ selected from the group consisting  
of chitosan, dimethylaminoethyl methacrylate/methyl  
methacrylate/butyl methacrylate copolymer, and polyvinyl acetal  
diethylaminoacetate ~~or mixtures thereof~~.

6. (Currently Amended) The formed product ~~A composition for disintegration in lower gastrointestinal tract~~ according to claim 1, ~~characterized in that the~~ wherein compound <A> is cystine and the polymer <B> is at least chitosan.

7. (Currently Amended) The formed product ~~A composition for disintegration in lower gastrointestinal tract~~ according to claim 3, ~~characterized in that~~ wherein the substance that controls the disintegration rate ~~at~~ in the large intestine of the lower gastrointestinal tract is at least one substance ~~that controls disintegration rate at the lower gastrointestinal tract optionally~~ selected from the group consisting of ethylcellulose, agar, pectin metal salt, carrageenin, gelatin, pectin, starch, cellulose, dimethylaminoethyl methacrylate/methylmethacrylate/butylmethacrylate copolymer and polyvinylacetal diethylaminoacetate.

8. (Currently Amended) The formed product of claim 1, wherein the formed product is a pharmaceutical or diagnostic composition ~~for releasing an active ingredient <C> in lower gastrointestinal tract, comprising a formed product of the composition according to claim 1.~~

9. (Currently Amended) The formed product according to claim 8, wherein the ~~formed product contains the~~ active ingredient <C> is therapeutic.

10. (Currently Amended) A formed product according to claim ~~8 or 9~~ 1, wherein the formed product is a capsule, a film, a sheet, or a coating film.

11. (Currently Amended) The formed product ~~A preparation for release in lower gastrointestinal tract, characterized in that an active ingredient <C> and the composition for disintegration in lower gastrointestinal tract~~ according to claim 1 wherein the formed product is are coated with an enteric polymer film.

12. Cancel

13. (Currently Amended) A system for per-oral ~~peroral~~ uptake of a material desired to be delivered to the large intestine of the lower gastrointestinal tract and selective release in the ~~lower gastrointestinal tract, characterized in that~~ large intestine wherein characterized in that the formed product ~~composition for disintegration in lower gastrointestinal tract~~ according to claim ~~1~~ 11 and an enteric polymer film are is used.

14. Canceled

15. (NEW) The formed product of claim 1, wherein compound <A> is contained in the product in a ratio of amounts of 1 to 90% by weight to 10 and polymer <B> is contained in the product in a ratio of amounts of 99 % by weight.

16. (NEW) A method for delivering an active ingredient to a large intestine part of lower gastrointestinal tract; comprising the steps of:

- (a) orally administering the formed product of claim 11;
- (b) dissolving the enteric polymer film in a small intestine;
- (c) forming microfine holes in the matrix where particles of compound <A> are present in the polymer <B>;
- (d) decomposing the polymer <B> by enterobacteria and/or softening, swelling or dissolving the polymer <B> by a pH in the range of from about 6.8 to a lower pH in the large intestine; and
- (e) disintegrating the matrix to selectively release the active ingredient in the large intestine.

17.(NEW) A method for selectively delivering an active ingredient to a large intestine part of lower gastrointestinal tract, comprising the steps of:

orally administering the formed product of claim 1, wherein when said formed product passes through said gastrointestinal tract, said active ingredient is selectively released in said lower gastrointestinal tract.

18. (NEW) A formed product for releasing a content in the large intestine part of the lower gastrointestinal tract, comprising:

(1) an inner core comprising an active ingredient <c> to be delivered to the large intestine;

(2) a disintegration layer surrounding said inner core comprising:

particles comprising at least one compound selected from the group consisting of L-cystine, D-cystine, DL-cystine, diglycyl cystine, cystamine, L-cystinyldiglycine, glutathione disulfide, and thioglycolic acid disulfide or  $\text{HOOC-R-S-S-R-COOH}$ , wherein R represents a lower alkylene group; and

a polymer <B> selected from the group consisting of chitosan, dimethylaminoethyl methacrylate/methyl metacrylate/butyl metacrylate copolymer, polyvinyl acetal diethylaminoacetate or mixtures thereof,

wherein the disintegration layer is stable in a small intestinal at a pH of about 6.8, but when in the large intestine, the particles of compound <A> are dissolved forming

microfine holes in the matrix of polymer <B> for liquid of the large intestine contents to enter the matrix;

(3) optionally an enteric coating surrounding said disintegration layer.

19. (NEW) A capsule for releasing a content in the large intestine part of the lower gastrointestinal tract, comprising:

(1) an inner space to be filled by the content;

(2) a disintegration layer forming said inner space comprising:

particles comprising a compound <A> having a molecular weight of 1,000 or less and having a disulfide bond; and

a polymer <B> having a molecular weight of above 1,000 which forms a matrix in which said particles are dispersed,

and having a property of being decomposed by enterobacteria, and/or a property of being softened, swelled or dissolved due to a pH in the range of from about 6.8 to a lower pH present in the large intestine, wherein the disintegration layer is stable in the small intestine at a pH of about 6.8, but when in the large intestine, the particles of compound <A> are dissolved forming microfine holes in the matrix of polymer <B> for liquid of the large intestine contents to enter the matrix;

(3) optionally an enteric coating surrounding said disintegration layer.